



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

*A. Rathman*  
*J. Smith*  
*F*

DEC 18 1989

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of  
Myclobutanil in/on Almonds and Almond Hulls, PP#9G3786.

FROM: Rita Briggs, Ph.D. *RB*  
Dietary Risk Evaluation System (DRES) Staff  
HED/SACB (H7509C)

THROUGH: J. Robert Tomerlin, Ph.D. *JRT*  
Acting DRES Program Manager  
HED/SACB (H7509C)

*JAR 11/18/89*

TO: Susan Lewis/Chambliss, PM Team 21  
Insecticide-Rodenticide Branch  
Registration Division

Action Requested

To estimate dietary exposure to myclobutanil using published tolerances and the proposed experimental use permit (EUP) on almonds.

Discussion

1. Toxicology Endpoint: The routine chronic DRES analysis used a reference dose (ADI) of 0.025 mg/kg body weight/day, based upon a NOEL of 2.49 mg/kg body weight/day and an uncertainty factor of 100 from a 2-year rat feeding study. This value has been approved by HED (01/27/88) and Agency (02/25/88) reference dose committees.
2. Residue Information: Food uses evaluated were published tolerances for almonds from 40 CFR 180.443, 185.4350 and 186.4350 and the temporary tolerance (0.1 ppm) incurred under the experimental use permit. Since almond hulls are an animal feed and the established tolerances for residues in meat, milk, poultry and eggs are considered by DEB to be adequate to cover secondary residues (J. Smith memo, 12/6/89), the tolerance on almond hulls was not included in the present analysis. A summary of the residue information used in the analysis is attached as Table 1.
3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. TMRC summaries for

## Myclobutanil Dietary Exposure Analysis, page 2

all DRES population groups are shown in Table 2 and discussed in the next section.

4. Dietary Risk Assessment: The revised DRES analysis which includes the proposed temporary tolerance for residues of myclobutanil in/on almonds indicates that dietary exposures do not exceed the reference dose (ADI) for any of the population groups. Table 2 shows that the total exposure estimate for the overall U.S. population is 0.001470 mg/kg/day which represents 5.9% of the ADI. The total exposure estimates for the two most highly exposed subgroups, non-nursing infants and children aged 1-6, are 31% and 18% of the ADI, respectively. The proposed temporary tolerance adds approximately 0.000001 mg/kg/day to the total exposure for each of the DRES population groups. This represents no more than 0.002% of the ADI. Therefore, the incremental exposures to myclobutanil from the proposed temporary tolerances on almonds are negligible.

## Attachments

cc: DRES (Tomerlin), DEB (Loranger), Caswell #723K, TOX (Hurley)

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 723K

DATE: 12/11/89

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Rally/Systane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: Negative- 2 species.	Testicular atrophy.  No evidence of oncogenic- ity in rats or mice; how- ever MTD's may not have been reached.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.  ADI based on actual food consumption.	HED complete 04/10/87. HED reassess 01/27/88. EPA verified 02/25/88.  On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM) PENDING	PUBLISHED
01014AA	GRAPES-FRESH	7F3476			1.000000
01014DA	GRAPES-RAISINS	7H5524			10.00000 H
01014JA	GRAPES-JUICE	7F3476			1.000000
03001AA	ALMONDS	9G3786	0.100000		
04001AA	APPLES-FRESH	7F3476			0.500000
04001DA	APPLES-DRIED	7F3476			0.500000
04001JA	APPLES-JUICE	7F3476			0.500000
43058AA	WINE AND SHERRY	7F3476			1.000000
50000DB	MILK-NON-FAT SOLIDS	7F3476			0.050000
50000FA	MILK-FAT SOLIDS	7F3476			0.050000
50000SA	MILK SUGAR (LACTOSE)	7F3476			0.050000
53001BA	BEEF-MEAT BYPRODUCTS	7F3476			0.050000
53001BB	BEEF(ORGAN MEATS)-OTHER	7F3476			0.050000
53001DA	BEEF-DRIED	7F3476			0.050000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	7F3476			0.050000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	7F3476			0.050000
53001LA	BEEF(ORGAN MEATS)-LIVER	7F3476			0.300000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	7F3476			0.050000
53002BA	GOAT-MEAT BYPRODUCTS	7F3476			0.050000
53002BB	GOAT(ORGAN MEATS)-OTHER	7F3476			0.050000
53002FA	GOAT(BONELESS)-FAT	7F3476			0.050000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	7F3476			0.050000
53002LA	GOAT(ORGAN MEATS)-LIVER	7F3476			0.300000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	7F3476			0.050000
53003AA	HORSE	7F3476			0.050000
53005BA	SHEEP-MEAT BYPRODUCTS	7F3476			0.050000
53005BB	SHEEP(ORGAN MEATS)-OTHER	7F3476			0.050000
53005FA	SHEEP(BONELESS)-FAT	7F3476			0.050000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	7F3476			0.050000
53005LA	SHEEP(ORGAN MEATS)-LIVER	7F3476			0.300000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	7F3476			0.050000
53006BA	PORK-MEAT BYPRODUCTS	7F3476			0.050000
53006BB	PORK(ORGAN MEATS)-OTHER	7F3476			0.050000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	7F3476			0.050000
53006KA	PORK(ORGAN MEATS)-KIDNEY	7F3476			0.050000
53006LA	PORK(ORGAN MEATS)-LIVER	7F3476			0.300000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	7F3476			0.050000
55008BA	TURKEY-BYPRODUCTS	7F3476			0.020000
55008LA	TURKEY-GIBLETS (LIVER)	7F3476			0.020000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	7F3476			0.020000

TABLE 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 723K

DATE: 12/11/89

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Rally/Systane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: Negative- 2 species.	Testicular atrophy.  No evidence of oncogenic- ity in rats or mice; how- ever MTD's may not have been reached.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.  ADI based on actual food consumption.	HED complete 04/10/87. HED reassess 01/27/88. EPA verified 02/25/88.  On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	7F3476			0.020000
55008MC	TURKEY-UNSPECIFIED	7F3476			0.020000
55013BA	POULTRY,OTHER-BYPRODUCTS	7F3476			0.020000
55013LA	POULTRY,OTHER-GIBLETS(LIVER)	7F3476			0.020000
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	7F3476			0.020000
55014AA	EGGS-WHOLE	7F3476			0.020000
55014AB	EGGS-WHITE ONLY	7F3476			0.020000
55014AC	EGGS-YOLK ONLY	7F3476			0.020000
55015BA	CHICKEN-BYPRODUCTS	7F3476			0.020000
55015LA	CHICKEN-GIBLETS(LIVER)	7F3476			0.020000
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	7F3476			0.020000
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	7F3476			0.020000

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 12/11/89

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Rally/Systane) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: Negative- 2 species.	Testicular atrophy.  No evidence of oncogenic- ity in rats or mice; how- ever MTD's may not have been reached.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.  ADI based on actual food consumption.	HED complete 04/10/87. HED reassess 01/27/88. EPA verified 02/25/88.  On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.001469	0.001470	5.878704	0.001120		
U.S. POPULATION - SPRING SEASON	0.001301	0.001301	5.203012	0.000964		
U.S. POPULATION - SUMMER SEASON	0.001375	0.001376	5.502196	0.000892		
U.S. POPULATION - FALL SEASON	0.001624	0.001624	6.497048	0.001236		
U.S. POPULATION - WINTER SEASON	0.001578	0.001579	6.314124	0.001392		
NORTHEAST REGION	0.001691	0.001691	6.765628	0.000944		
NORTH CENTRAL REGION	0.001440	0.001441	5.762232	0.000904		
SOUTHERN REGION	0.001153	0.001153	4.612652	0.000812		
WESTERN REGION	0.001762	0.001763	7.050852	0.002220		
HISPANICS	0.001583	0.001584	6.334224	0.000344		
NON-HISPANIC WHITES	0.001518	0.001519	6.074392	0.001272		
NON-HISPANIC BLACKS	0.001108	0.001109	4.434472	0.000596		
NON-HISPANIC OTHERS	0.001394	0.001394	5.577432	0.000356		
NURSING INFANTS (< 1 YEAR OLD)	0.003826	0.003826	15.302900	0.000132		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.007767	0.007767	31.069432	0.000856		
FEMALES (13+ YEARS, PREGNANT)	0.001021	0.001021	4.083212	0.000724		
FEMALES 13+ YEARS, NURSING	0.001385	0.001385	5.539564	0.000364		
CHILDREN (1-6 YEARS OLD)	0.004485	0.004486	17.942772	0.001692		
CHILDREN (7-12 YEARS OLD)	0.002172	0.002173	8.691048	0.001444		
MALES (13-19 YEARS OLD)	0.001200	0.001200	4.801376	0.000796		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.001030	0.001030	4.119640	0.000856		
MALES (20 YEARS AND OLDER)	0.000864	0.000864	3.457832	0.001152		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000868	0.000869	3.474696	0.001000		

\*Current TMRC does not include new or pending tolerances.

\*\*New TMRC includes new, pending, and published tolerances.